



# Accounting for Prescription Drugs' Unforeseen Risks: A Regulatory Alternative to Tort Liability

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## Introduction

In the context of a heavily regulated industry like prescription drugs, tort law is traditionally viewed as an effective backstop to regulation,<sup>1</sup> providing added incentive for drug manufacturers to adhere to regulations of the Food and Drug Administration (FDA) and accounting for risks unknown at the time of regulation. However, I argue that in some cases—and in particular where drug manufacturers will be held liable for risks that were unforeseen at the time of FDA approval—tort liability can distort manufacturers’ incentives and may lead to a suboptimally high level of risk avoidance.

Nonetheless, I reject the contention that simple preemption of all tort liability or a complete regulatory compliance defense is an appropriate solution.<sup>2</sup> Such an approach would eliminate valuable incentives created by the tort system for the on-going, post-market monitoring of prescription drugs. I therefore propose an alternate system that harnesses the resources of the private sector to invest the optimal amount in researching prescription drugs post-marketing and makes this information available to the parties best suited to weigh any newly discovered risks, without holding manufacturers liable for these risks in such a way as to distort the FDA’s initial pre-market balancing.

In Part I, I discuss the distorting effect of liability under a strict liability standard. In Part II, I will show how currently predominant theories of liability fail to address the problems

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<sup>1</sup> See, e.g., Joseph A. Page *Liability for Unreasonably and Unavoidably Unsafe Products: Does Negligence Doctrine Have a Role to Play?*, 72 CHI.-KENT L. REV. 108 (1996) (“Damage suits by victims . . . serve as an alternative method of reviewing decisions to place [regulated] products on the market.”).

<sup>2</sup> See, e.g., Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 335 (1985) [hereinafter “Huber, *Safety and the Second Best*”] (“Requiring—or at least strongly encouraging—the courts to respect the comparative risk choices made by competent, expert agencies would inject a first, small measure of rationality into a judicial regulatory system that currently runs quite wild.”).

outlined in Part I. In Part III, I will suggest that a negligence approach, properly designed, would address the concerns expressed in Part I, but I will reject the notion that courts can successfully operate under a negligence standard in such complex, technical suits. In Part IV, I will provide a proposal for a regulatory alternative implementing a negligence approach.<sup>3</sup>

## **I. The undesirability of unforeseen-risk liability.**

Before a prescription drug can be marketed, the FDA subjects it to a rigorous cost-benefit analysis.<sup>4</sup> FDA approval of a drug reflects a determination that the drug's social benefits (and the social benefits of the pre-marketing approval process) outweigh its social costs (and the social costs of further pre-approval investigation).<sup>5</sup> I argue that, given the unforeseen risks of prescription drugs at the time of FDA approval, tort liability does not reinforce FDA's determinations; instead, we should expect such liability to encourage firms to engage in less activity than would be permitted by the FDA. I argue that this is undesirable, as we should favor agency determinations regarding optimal pre-market testing over those made by firms facing the prospect of liability for risks unforeseen at the time of FDA approval.

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<sup>3</sup> See, e.g., PETER SCHUCK, REG-MARKETS CENTER, FDA PREEMPTION OF STATE TORT LAW IN DRUG REGULATION: FINDING THE SWEET SPOT 19 (August 2008).

<sup>4</sup> See THE CDER HANDBOOK, *The New Drug Development and Review Process*, available at <http://www.fda.gov/cder/handbook/>; Areta L. Kupchyk & Josephine M. Torrente, *R&D 101: Legal Issues During Research and Development*, in PHARMACEUTICAL LAW 2006: ACROSS THE PRODUCT LIFE CYCLE, PRACTICING LAW INSTITUTE (2006) (outlining FDA requirements pertaining to new drug development and approval).

<sup>5</sup> See *infra* notes 8–13 and accompanying text; Michael A. Friedman, et al., *The Safety of Newly Approved Medicines: Do Recent Market Removals Mean There Is a Problem?* 281 JAMA 1728, 1732 (May 12, 1999) (“In evaluating drugs for approval, the FDA uses a pragmatic standard: do the demonstrated benefits outweigh the known risks. . . . However . . . drug approvals are made on the basis of limited information and more is inevitably learned as a drug becomes widely used.”); *cf.* Brown v. Superior Court, 751 P.2d 470, 479 (Cal. 1993) (observing that sometimes “public policy favors the development and marketing of beneficial new drugs, even though some risks, perhaps serious ones, might accompany their introduction, because drugs can save lives and reduce pain and suffering”).

**A. Undermining FDA determinations of marketability through liability for unforeseen risk.**

In theory, if the FDA is operating under an optimal negligence standard, subjecting manufacturers to strict liability for harms caused by their products should serve only to reinforce the incentives established by the FDA. After all, the optimal negligence and strict liability standards would create the same incentives for manufacturers to eliminate all efficiently avoidable risk. Meanwhile, in any case where the cost of harm resulting from a risk was less than the cost of eliminating that risk, a manufacturer subject to strict liability would have no added incentive to change its behavior—it would simply bear the cost of harm.<sup>6</sup> It is therefore not obvious that holding drug manufacturers liable in tort for injuries caused by their products will provide them with conflicting, or at least inconsistent, incentives, as some critics have assumed.<sup>7</sup>

However, the FDA in evaluating drugs can never operate under a perfect negligence standard. This is because all prescription drugs at the time of approval have “unforeseen risks.” By this I mean those risks of a drug that cannot be known without close monitoring of widespread use over a long period of time; even after such long-term, widespread use, a drug’s safety can likely never be guaranteed.<sup>8</sup> Implicit in the FDA’s approval of a new drug for

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<sup>6</sup> Such a system, therefore, would achieve what Guido Calabresi identifies as “the principle function of accident law[:] to reduce the sum of the costs of accidents and the costs of avoiding accidents.” GUIDO CALABRESI, *THE COSTS OF ACCIDENTS: LEGAL AND ECONOMIC ANALYSIS* 26 (1970).

<sup>7</sup> See SCHUCK, *supra* note 3, at 5; Alfred W. Cortese, Jr. & Kathleen L. Blaner, *The Anti-Competitive Impact of U.S. Product Liability Laws: Are Foreign Businesses Beating Us at Our Own Game?*, 9 J. L. & COMM. 167, 193 (1989).

<sup>8</sup> See Friedman, et al., *supra* note 5, at 1732–33; “Drug Safety,” Hearings Before a Subcommittee of the House Committee on Government Operations, 88th Congress 2d Session (1964) (testimony of George Larrick) [hereinafter “Larrick testimony”] (“No plan of clinical

marketing is a determination not only that the drug's known and anticipated benefits outweigh its known and anticipated costs,<sup>9</sup> but that the costs of continued pre-market testing are greater than its benefits.<sup>10</sup>

Engaging in longer-term clinical trials or otherwise extending the pre-market approval

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investigation, even the most expensive, can be expected to give all of the information that will be revealed by general marketing and use of a new drug.”); Richard A. Merrill, *Compensation for Prescription Drug Injuries*, 59 VA. L. REV. 1, 17–20 (1973); Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 YALE J. HEALTH POL’Y L. & ETHICS 587, 588–89 (2005) (“premarketing studies cannot guarantee product safety”) (internal quotation marks omitted).

Catherine Struve identifies various types of risks that “[c]linical trials normally will fail to reveal. . . . those that occur relatively rarely, those involving relatively subtle increases in the risk of already common problems, those that disproportionately affect a population subset not represented in the trial, and those with a long latency period.” *Id.* Consider, for instance, the drug Parnate, whose “infrequent but serious adverse reactions [were] revealed only with use of the drug in large patient populations,” PETER BARTON HUTT, ET AL., FOOD AND DRUG LAW, CASES AND MATERIALS, 749 (2007) (citing “Drug Safety,” Hearings Before the Intergovernmental Relations Subcommittee of the House Committee on Government Operations, 89th Congress, 1st Session (1965) (statement of Joseph F. Sadusk, Jr.)), and Vioxx, which may present a risk of “about six or seven heart attacks for every 1,000 patients who took the drug . . . a risk [that] could have been easily missed, even with a clinical trial that included 10,000 patients or more,” Scott Gottlieb, *The Price of Too Much Caution*, THE NEW YORK SUN, Dec. 22, 2004, at 8. Another category of unexpected adverse reactions that are likely to surface only through widespread use of a prescription drug are those that occur as a result of interactions among drugs. *See, e.g.*, Friedman, et al., *supra* note 5, at 1729 (discussing the drug Mibefradil, which interacted with other drugs to create “adverse events of a magnitude and seriousness not detected in the premarket clinical trials”).

<sup>9</sup> Larrick testimony, *supra* note 8 (“The decision to approve a drug for marketing, or to withdraw an earlier approval, requires a weighing of the benefit to be expected from use of the product against the risk inherent in its use.”)

<sup>10</sup> *See* Victor E. Schwartz & Phil Goldberg, *A Prescription for Drug Liability and Regulation*, 58 OKLA. L. REV. 135, 155 (2005) (“The FDA uses its formal rule-making process to review [manufacturers’ pre-market] research and determine if more research is needed in order for an application to be complete. . . . Thus, for the FDA’s approval process to have any meaning, the requirements of the FDA’s NDA [new drug application] program must set the legal standard for what constitutes “reasonable” research for each prescription drug.”). *Cf.* Merrill, *supra* note 8, at 20 (“The drug approval system . . . necessarily contemplates that drugs will be available for general use before all of their hazards are known.”); Richard A. Nagareda, *In The Aftermath of the Mass Tort Class Action*, 85 Geo. L. J. 295, 342 (1996) (arguing that political institutions, when faced with an activity accompanied by risks that are of an unknown level and nature, must weigh the possibility of risk and the level of uncertainty against the likely benefits of the activity).

process could make the FDA and manufacturers aware of risks that are not revealed under the current system, but such changes would delay drug availability and increase the costs of development.<sup>11</sup> FDA approval of a new drugs rests on the determination that discovering the drug's then-unforeseen risks pre-marketing is not worth delaying the drug's availability or driving up its price.<sup>12</sup> That such tradeoffs are a part of the drug approval calculus has at times been made explicit. For instance, in 1992, Congress passed the Prescription Drug User Fee Act, designed to expedite the drug approval process.<sup>13</sup> Congress took steps to speed up the approval process even though such acceleration meant that fewer risks would be revealed pre-marketing. For instance, speedier approval in the United States means that drugs are less likely to be approved in other countries first, which, in turn, means that U.S. regulators have less of an opportunity to observe, pre-approval, whether unexpected adverse events occur when the drug is

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<sup>11</sup> U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION, TASK FORCE ON RISK MANAGEMENT, MANAGING THE RISKS FROM MEDICAL PRODUCT USE: CREATING A RISK MANAGEMENT FRAMEWORK, at 11 (May 1999) [hereinafter "TASK FORCE ON RISK MANAGEMENT"]. Such delays and costs would be adding to the estimated ten to fifteen years and "well over \$1 billion" it already takes a new chemical entity new drug to be developed and approved. See HUTT ET AL., *supra* note 8, at 557. Taken to the extreme, an effort to determine all risks pre-marketing would completely halt the development and availability of new drugs. As one observer has put it, "Were safety the only measure, the agency's job would be easy—and our medicine chests would be empty." Bernadine Healy, *What is a 'Safe' Drug?*, U.S. NEWS & WORLD REPORT, Dec. 13, 2004, at 37.

<sup>12</sup> See Schwartz & Goldberg, *supra* note 10, at 155; Struve, *supra* note 8, at 596 ("The FDA's mission of protecting consumer safety dictates rigorous premarketing review, but its mandate to foster innovation creates a countervailing pressure."); Gottlieb, *supra* note 8 ("With this additional testing, the benefits of an off chance of discovering a rare side effect before a new drug is approved is eventually outweighed by the cost of keeping promising drugs from the patients."). Scott Gottlieb illustrates his point that "[e]ven delaying seemingly ordinary drugs can have dramatic consequences on the public health" with figures estimating the number of injuries or deaths that occurred during the approval processes of several drugs and that might have been avoided by those drugs. *Id.* See also Huber, *Safety and the Second Best*, *supra* note 2 at 308–09 (observing that delay in technological change for fear of introducing new risks does not amount to the avoidance of risk but to favoring old risks that continue to proliferate if they are not displaced).

<sup>13</sup> Friedman, et al., *supra* note 5 at 1730; TASK FORCE ON RISK MANAGEMENT, *supra* note 11, at 16–17.

used by a wider, more diverse, and less controlled population over a longer period of time than is permitted by clinical studies.<sup>14</sup> Similarly, the FDA will sometimes subject certain drugs to a less rigorous pre-approval regime when it determines that the costs of delaying their availability outweighs the benefits of further testing.<sup>15</sup>

The extent of testing and the timing of availability are therefore part of the FDA's calculus when it approves a new drug. At the time of approval, the FDA determines that further testing is not worth the social costs of such testing, but it does so in light of imperfect information: as it weighs the costs and benefits of a drug's availability, the FDA cannot know the exact value of the drug's unforeseen risks, and so it assigns these risks a social value in relation to the known costs and benefits of approval versus non-approval.

Given the imperfection of the FDA's calculus, holding manufacturers strictly liable for unanticipated adverse effects would likely distort their incentives such that the calculus they

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<sup>14</sup> See Friedman, et al., *supra* note 5 at 1731–32.

<sup>15</sup> *Id.* at 1733 (“Some . . . pharmaceuticals—those intended for serious or life-threatening diseases that lack satisfactory alternatives—are approved with a much smaller safety data than is traditional, with much more information gathering deferred into the postmarket period. In these cases, too, the FDA and the community are willing to take greater safety risks due to the serious nature of the illness being treated.”). For another example of the FDA and Congress balancing the costs and benefits of further pre-market investigation, see Struve, *supra* note 8, at 596–97.

In 1997, finding that "prompt approval of safe and effective new drugs and other therapies is critical to the improvement of the public health," Congress directed the FDA to employ the "least burdensome" methods of evaluating products in the premarket notification and premarket approval processes. Pursuant to this mandate, the FDA has declared that premarket approval can sometimes be based on "well-designed bench and/or animal testing" rather than clinical tests. Moreover, the FDA will consider the extent to which measures such as postmarketing trials can substitute for premarket scrutiny. Though clinical data are in any event not required for most premarket notifications, the FDA responded to the "least burdensome" directive by emphasizing that "substantial equivalence" determinations should also be streamlined.

*Id.* (footnotes omitted).

would apply in deciding whether to market their drugs would not align with the calculus employed by the FDA in weighing the social costs and benefits of making those drugs available. Even after the FDA has determined that it would be socially beneficial to have a given drug on the market, the drug's manufacturer might hesitate to make it available due to the threat of liability for unforeseen risks. This is because the value assigned to these unknown risks by the FDA will not necessarily align with the real-world value of the injuries they will eventually cause, for which the manufacturer will be held liable under a system of strict liability.

One obvious response to this observation is that tort liability is not properly characterized as distorting in this context, but is corrective: it incentivizes manufacturers to minimize the *actual* combined costs of injury and injury avoidance, rather than the costs as imperfectly imagined by the FDA.<sup>16</sup> However, if a risk that is unknown to the FDA at the time of approval is also unknown to the manufacturer, the threat of liability for injuries resulting from that risk cannot be said to provide optimal incentives for the manufacturer. A drug manufacturer cannot act rationally in response to the threat of liability for harms resulting from a truly unforeseen risk.<sup>17</sup> A firm facing such liability<sup>18</sup> is likely to respond with less activity and greater care than

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<sup>16</sup> Cf. Clayton P. Gillette & James E. Krier, *Risk, Courts, and Agencies*, 138 U. PENN. L. REV. 1027, 1057 (1990) (arguing that tort liability corrects for under-regulation of risk by agencies).

<sup>17</sup> This argument holds true only where a risk is truly unforeseen to both the manufacturer and the FDA, so that the manufacturer cannot make an ex ante calculation of a risk's likely costs compared to the cost of precautions reasonably designed to learn more about or avoid those risks. Where a manufacturer has some notion of the nature of the risk, the threat of strict liability might encourage it to take rational steps to learn more about those risks before marketing. However, assuming the manufacturer and the FDA have equal information regarding possible risks, the FDA will already have determined it socially beneficial to market the drug without taking those additional steps. Unless the manufacturer can fully internalize the social benefits of making its drug available, internalizing the full costs through liability will distort the manufacturer's incentives to adhere to the FDA's balancing of costs and benefits. The result, as one observer writes is "to modify corporate behavior that never was unreasonable, that, in fact, was beneficial to society." Cortese & Blaner, *supra* note 7, at 185 (1989).



has been deemed optimal by the FDA or, if profitable, to raise the price of its products until it deems marketing worthwhile.<sup>19</sup> As neither of these approaches can reflect optimal precautions, given the extent of uncertainty,<sup>20</sup> neither is desirable. Instead, the tort system should not undermine the FDA's policy decision that the benefits of marketing a drug at the time of its approval outweigh its risks.

### **B. Firms' necessarily irrational response to the threat of liability for unforeseen risks.**

A manufacturer that has received FDA approval to market its drug, but which faces an indeterminate threat of liability for unforeseeable risks, is taking a gamble if it decides to market its product.<sup>21</sup> The threat of such liability cannot be said to create a rational basis for action ex

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<sup>18</sup> As Peter Huber notes, this threat is a serious one, often of bankruptcy. Peter Huber, *Of Pills and Profits: In Defense of Big Pharma*, MANHATTAN INSTITUTE FOR POLICY RESEARCH, COMMENTARY (Jul.–Aug. 2006), [http://www.manhattan-institute.org/html/\\_commentary-of\\_pills\\_and\\_profits.htm](http://www.manhattan-institute.org/html/_commentary-of_pills_and_profits.htm) [hereinafter “Huber, *Of Pills and Profits*”]. Below, I will address why liability insurance is not enough to ensure manufacturers' rational response to the threat of unforeseeable and potentially bankrupting liability.

<sup>19</sup> See *id.*; Cortese & Blaner, *supra* note 7, at 187–89, 190–91 (discussing firms' possible responses to risks from existing products and from products not yet on the market, and their respective drawbacks); Scott S. Evans, *Dynamic Incentives: Improving the Safety, Effectivity, and Availability of Medical Products Through Progressively Increasing Damage Caps for Manufacturers*, 2007 U. ILL. L. REV. 1069, 1071 (“In the end, manufacturers' inability to gauge potential liability for unforeseeable risks stifles research and development, thereby reducing availability.”).

<sup>20</sup> Cf. E. Donald Elliott, *Why Punitive Damages Don't Deter Corporate Misconduct Effectively*, 40 ALA. L.J. 1058 (1989) (when an actor does not know how to gear behavior specifically to avoid penalty, all it can do is act less).

<sup>21</sup> Although strict liability is often applied in situations where the actor is deemed unable to have avoided the risk, the actor is usually aware of the nature of the risk he creates. For instance, a company that uses dynamite can foresee the risk that the dynamite will explode accidentally, can calculate a probability that it might, and can exit the market or raise its prices accordingly to off-set any expected and unavoidable liability. By contrast, a drug manufacturer who anticipates liability for the unforeseen risks of its product does not have similar information on which to base its decision. This is why, for instance, the Third Restatement of Products Liability distinguishes “[t]he issue of foreseeability of risk of harm . . . in the case of products

ante. To minimize its liability exposure, the firm might decide to delay marketing its drug or may not market it at all, but the manufacturer's decision not to act is made in the absence of vital information: if a risk is truly unknown at the time of FDA approval, in that its nature or its likelihood cannot be surmised, the firm cannot predict the type or the magnitude of the risk it hopes to minimize.<sup>22</sup> Any decision not to market therefore cannot be said to reflect optimal precautions. Similarly, if the firm decides to market its drugs but raise its prices to account for some potential future liability, the amount cannot be determined on any basis that is directly and rationally connected to the liability it will face.

The argument that firms cannot act rationally in response to the threat of liability for unknown risks would not hold if drug manufacturers had access to comprehensive liability insurance. If manufacturers could purchase insurance to cover litigation costs arising from any risks unforeseen at the time of FDA approval, they would be risk neutral with regard to these risks, and their determination whether to market their products would be unaffected. However, it is not clear that pharmaceutical companies do reliably have access to such insurance. In 1993, the U.S. Congress, Office of Technology Assessment (OTA) reported:

“Most of the pharmaceutical firms interviewed by OTA indicated that they can no longer get any basic insurance coverage in the traditional liability insurance market. . . . Consequently, pharmaceutical manufacturers have

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such as prescription drugs . . . . Risks attendant to use and consumption of these products may, indeed, be unforeseeable at the time of sale.” The Restatement therefore stipulates that “[t]he harms that result from unforeseeable risks—for example, in the human body’s reaction to a new drug, medical device, or chemical—are not a basis of liability.” RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2, Comment m (1998) [hereinafter “RESTATEMENT (THIRD)”]. See also *Brooks v. Beech Aircraft Corp.*, 902 P.2d 54, 63 (N.M. 1995) (suggesting that strict liability is appropriate only where the manufacturer is aware of the risks posed by any given product design and is aware of alternative designs).

<sup>22</sup> Heidi Li Feldman shows that, even when a particular risk has been identified, and some evidence has been gathered that the drug presents that risk, the probability that the drug did in fact present the risk can be *entirely* unknown. Heidi Li Feldman, *Science and Uncertainty in Mass Exposure Litigation*, 74 TEX. L. REV. 1 (1995).

increasingly self-insured to compensate for lost basic insurance coverage by setting aside reserves to cover expected losses, establishing special lines of credit to cover unanticipated liability losses, and establishing ‘captured’ insurance companies that are wholly or primarily owned by the insured pharmaceutical firm and have no other policyholders.”<sup>23</sup>

Other observers posit that, as the standards of strict liability have become more widely adopted by courts, and as findings of liability have in turn become less predictable, liability insurance for unforeseen risks has become less available and more expensive where it is available.<sup>24</sup>

Aside from anecdotal evidence about the unavailability of insurance particularly for investigational or experimental drugs,<sup>25</sup> there appears to be little if any empirical research

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<sup>23</sup> U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, PHARMACEUTICAL R&D: COSTS, RISKS AND REWARDS, OTA-H-522, 172 (1993) [hereinafter “OFFICE OF TECHNOLOGY ASSESSMENT”]. See also Cortese & Blaner, *supra* note 7, at 190 (“Manufacturers cannot protect against these [unknown] risks with insurance, because insurance often is not available for innovative products.”). For a discussion of biotechnology firms’ difficulty obtaining liability insurance, see Dan L. Burk & Barbara A. Boczar, *Biotechnology and Tort Liability: A Strategic Industry at Risk*, 55 U. PITT. L. REV. 830 (1994) (“In the case of biotechnology, the usual safeguard against disastrous liability—insurance—may not even be available. Product liability insurance is difficult for biotechnology companies to obtain and expensive when available.”).

Joachim Zekoll provides an account of the “liability insurance crisis” of the 1980s, which dramatically restricted firms’ access to insurance. *Liability for Defective Products and Services*, 50 AM. J. COMP. L. 155 (2002). His account suggests that tort rules can affect the availability and expense of insurance, so that increasing manufacturers’ exposure to liability can, in turn, decrease their access to insurance. *Id.* This observation counsels against dramatically expanding liability on the assumption that manufacturers can be insured against any increased exposure. See also Alice Platt Harris, *Brown v. Superior Court: A Tonic For Prescription Drug Manufacturers*, 16 WESTERN STATE U. L. REV. 753, 766 (1989) (noting a dramatic rise in the cost of liability insurance for pharmaceutical firms just between 1984 and 1986).

<sup>24</sup> Zekoll, *supra* note 23, at 155; Cortese & Blaner, *supra* note 7, at 182 (citing Richie, *The Two Faces of Strict Liability: It’s Stifling Progress and Hurting Business*, THE BRIEF, Fall 1989, at 16; George L. Priest, *The Current Insurance Crisis and Modern Tort Law*, 96 YALE L. J., 1521, 1536–37 (1987)).

<sup>25</sup> See, e.g., Philip M. Boffey, *Loss of Drug Relegates Many to Blindness Again*, N.Y. TIMES, Oct. 14, 1986, at C1 (noting patients’ inability to obtain investigational drug for neuromuscular disorders because liability insurance unavailable to manufacturer); Peter Huber, *Safety and the Second Best*, *supra* note 2, at 287 (noting the vaccine industry’s inability to obtain liability insurance to cover the production and sale of Swine Flu vaccine).

documenting the availability of product liability insurance for these risks.<sup>26</sup> Nonetheless, there is reason to believe that the generally observed shortage and expense of liability insurance across the pharmaceuticals field applies in particular to coverage of unknown risks.<sup>27</sup> To begin with, it is impossible for insurers to calculate the size of unknown risks. In addition, we can imagine that an insurance market for these types of risks would be particularly prone to adverse selection problems. Given manufacturers' superior access to information concerning the nature, development, and testing of their drugs, insurers would likely have difficulty determining whether certain risks were truly unknown by the manufacturer.

In short, it is doubtful that liability insurance is available to fully cover the costs of litigation for the unforeseen risks of prescription drugs. The risk-neutralizing effects of liability insurance generally therefore cannot be relied on to rebut the argument that prescription drug manufacturers will not act rationally when faced with the threat of liability for risks that are unforeseen at the time of FDA approval.

### **C. Avoiding the distorting incentives created by liability for unforeseen risk.**

Still, we might not be concerned with a firm's decision to delay or avoid marketing if we do not think the FDA, with the same lack of information, can make a better decision regarding

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<sup>26</sup> See OFFICE OF TECHNOLOGY ASSESSMENT, *supra* note 23, at 173 ("Systematic attempts to determine product liability costs borne by the pharmaceutical industry, and the impact of product liability on firms' R&D decisions, innovation, and drug safety would require data from several sources, much of which is currently unavailable.").

<sup>27</sup> See Cortese & Blaner, *supra* note 7, at 190 ("Because insurers cannot accurately determine the probability of the risks from the innovative products they are asked to insure, they refuse to provide insurance.") (citing Priest, *supra* note 24, at 1544–45).

the optimal amount of precaution to be taken pre-marketing.<sup>28</sup> However, although the FDA is in no better position than the firm to account *accurately* for unknown risk, neither is it in any worse of a position. Under these circumstances, the agency and not the firm should decide how to value this unforeseen risk. This decision, without any scientific basis, is inherently political.<sup>29</sup> How an unknown quantity of an unknown, possibly devastating, possibly mild, possibly non-existent risk should be accounted for should not turn on considerations such as the internal business structure of a manufacturer or its board's attitude towards risk. This decision is necessarily subjective; the subjective valuation of a public agency should be relied on before that of a manufacturing firm's management. To the extent that tort liability for unforeseen risk may encourage firms to deviate from the FDA's valuation of such risks, it is undesirable.

Tort liability for unforeseen risk is equally troubling because of its tendency to encourage firms to raise prices. Such price adjustment will have direct implications for individuals' access to drugs, as well as for equality of access.<sup>30</sup> One possibility to counter these effects would be for the government to correct them through subsidies or wealth transfer programs. For instance, the FDA might determine the social value of a drug and subsidize the manufacturer based on that

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<sup>28</sup> Cf. *Wyeth v. Levine*, 555 U.S. \_\_\_\_ (2009) (slip op., at 17) (emphasizing that FDA approval of a label merely sets a floor, and that a drug manufacturer is and should be free to add warnings to its product's label as it discovers new risks).

<sup>29</sup> See Nagareda, *supra* note 10, at 326 (arguing that in situations such as these, "the agency's determination of whether to regulate and how stringently to do so will entail 'choices that by their nature require basic policy determinations rather than resolution of factual controversies'" (quoting *Industrial Union Dep't, AFL-CIO v. Hodgson*, 499 F.2d 467, 474–75 (D.C. Cir.1974))).

<sup>30</sup> See Louis Lasagna, *The Chilling Effect of Product Liability on New Drug Development*, in *THE LIABILITY MAZE* 334, 335–336 (P. HUBER & R. LITAN eds. 1991). Consider especially experimental drugs and orphan drugs. See, e.g., Justin Gillis, *Patients Press Please for Cancer Drugs: Experimental Medicine in Short Supply*, *Wash. Post*, Apr. 7, 2002. Peter Huber notes that as firms' prices increase in the face of threatened tort liability, consumption will shift towards less expensive options, which might include non-consumption of the expensive product, in this case prescription drugs; "[t]his is a risk preference that is most probably hazardous to the public's health." Huber, *Safety and the Second Best*, *supra* note 2, at 315–16.

value, or the government might extend patent lengths or strengthen their preclusive effect where necessary to encourage firms to stay in the market and maintain affordable prices, despite the wildcard liability they face.<sup>31</sup> But programs like these begin to look absurd when we realize they are adopted for the purpose of negating the incentives created by liability. It would be far more sensible simply to eliminate the pressures of strict liability.<sup>32</sup>

Prescription drug manufacturers should not be held liable for those risks that are unforeseen at the time of approval. Instead, a system should be put in place that creates incentives for manufacturers to invest optimally in continued evaluation of their products post-marketing. As evidence of new risks arises, the FDA rather than the courts should be consulted, enabling the agency to modify its assessment of a drug as more information becomes available.

## **II. The failure of current tort liability approaches to address the problem of unforeseen risk.**

In Part I, I discussed the effects of holding drug manufacturer's strictly liable for injuries caused by their products. In this Part, I will show how the current system of tort liability fails to solve the problems I have identified. First, I will discuss traditional products liability doctrines. Second, I will look to the exceptions to traditional products liability, as encapsulated in comment k to the Second Restatement of torts, § 402(A), that courts sometimes apply to manufacturers of

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<sup>31</sup> See Merrill, *supra* note 8, at 119–20 (1973).

<sup>32</sup> The government's one-time agreement on this point is illustrated by its policies regarding the vaccine industry. The government realized that in order to keep vaccine prices under control without driving all vaccine manufacturers from the market, it had also to limit manufacturers' liability. See Rank A. Sloan et al., *The Fragility of the U.S. Vaccine Supply*, 351 NEW ENGLAND JOURNAL OF MEDICINE 23 (2004); Michael Greenberger, *The 800 Pound Gorilla Sleeps: The Federal Government's Lackadaisical Liability and Compensation Policies in the Context of Pre-Event Vaccine Immunization Programs*, 8 J. OF HEALTH CARE L. & POL. 7 (2005); Peter Huber, *Safety and the Second Best*, *supra* note 2, at 287–89.

prescription drugs.

### A. Traditional products liability.

Drug manufacturers might be held liable for unforeseen risks should traditional products liability principles apply to prescription drugs. Traditionally, products liability has been divided into three categories, attaching where a product has caused injury as a result of: a manufacturing defect, a design defect, or a failure to warn.<sup>33</sup> Liability within each of these categories might be applied under either a theory of negligence or a theory of strict liability.<sup>34</sup> For instance, two tests are frequently used to determine whether products are defectively designed—a consumer expectations test and a risk-utility balancing test<sup>35</sup>—and some formulations of these tests would hold manufacturers strictly liable. Under one formulation by the Illinois Supreme Court, for example, a manufacturer will be held liable under the consumer expectations test if its product “failed to perform as safely as an ordinary consumer would expect when used in an intended or

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<sup>33</sup> Angela C. Rushton, *Design Defects Under the Restatement (Third) of Torts: A Reassessment of Strict Liability and the Goals of a Functional Approach*, 45 EMORY L.J. 389, 396 (1996). Manufacturing defects, however, play little role in prescription drugs torts suits and will not be discussed here. See Richard L. Cupp, Jr., *Rethinking Conscious Design Liability for Prescription Drugs: The Restatement (Third) Standard Versus a Negligence Approach*, 63 GEO. WASH. L. REV. 76, 90 (1994) (“At least with regard to prescription drugs, defects usually are not related to mistakes in manufacture, but rather center around unwanted consequences of using the drug.”) (citing James A. Henderson, Jr. & Aaron D. Twerski, *A Proposed Revision of Section 402A of the Restatement (Second) of Torts*, 77 CORNELL L. REV. 1512, 1540 (1992)).

<sup>34</sup> David G. Owen, *Symposium: A Tribute to Professor David Fischer*, 73 MO. L. REV. 291, 297 (2008); *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 833 (Neb. 2000). Cf. David R. Geiger and Stephanie Copp Martinez, *Design and Warning Defect Claims Under Massachusetts Product Liability Law: Completing the Merger of Negligence and Warranty*, 43 BOSTON BAR J. 12 (1999) (observing that the Third Restatement of Torts is concerned with providing a definition of “defect” that should remain constant regardless of whether strict liability or negligence is applied); RESTATEMENT (THIRD), *supra* note 21, § 2, comment *n*, at 35–36.

<sup>35</sup> Owen, *supra* note 34, at 299.

reasonably foreseeable manner.”<sup>36</sup> Similarly, in Illinois a manufacturer will be held liable under the risk-utility test if its “product’s design proximately caused . . . injury and . . . on balance the benefits of the challenged design [do not] outweigh the risk of danger inherent in such designs.”<sup>37</sup> Both of these approaches are strict, in that neither considers the manufacturer’s knowledge at the time of production or marketing.

Product liability claims for design defect and failure to warn are decided on the basis of strict liability in a number of jurisdictions, rendering irrelevant the state of defendant’s knowledge at the time of production or marketing.<sup>38</sup> If such an approach were extended to prescription drugs, a prescription drug manufacturer could be held liable for injuries caused by its product, although the risk of such injuries were unknown to the manufacturer at the time of FDA approval.<sup>39</sup> Such liability is undesirable for the reasons outlined in Part I.

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<sup>36</sup> *Lamkin v. Towner*, 138 Ill.2d 510, 529 (Ill. 1990).

<sup>37</sup> *Id.*

<sup>38</sup> *See, e.g., Elmore v. Owens-Illinois, Inc.*, 673 S.W.2d 434, 438 (Mo. 1984) (“the sole subject of inquiry is the defective condition of the product and not the manufacturer’s knowledge, negligence or fault”); *Carreter v. Colson Equipment Co.*, 449 A.2d 326, 329–330 (Pa. Super. 1985) (holding that defendant’s knowledge or constructive knowledge is irrelevant in a products liability action, whether for design defect or failure to warn); *Little v. PPG Industries, Inc.*, 579 P.2d 940, 947 (Wash. App. 1978) (“[I]f [a] product has dangerous propensities even though they are unknown to the manufacturer and reasonable care has been taken to make and market the product unless the dangerous [sic] are obvious or known to the user, the manufacturer will be held strictly liable if it has not adequately warned the user of the dangers inherent in the use of the product by, for example, affixing a proper label.”). *See also*, RESTATEMENT (SECOND) OF TORTS § 402A (1965) [hereinafter “RESTATEMENT (SECOND)”] (“One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused . . . although the seller has exercised all possible care in the preparation and sale of his product . . . .”); *but see infra* Part II.B. (discussing comment k’s exception to § 402A’s application of strict liability for some prescription drugs).

<sup>39</sup> *See Page, supra* note 1, at 87 n.2 (“[T]he proposition that manufacturers may be liable for failing to design out unknowable risks is generally found in dictum.”) (citing *Cepeda v. Cumberland Eng’g Co.*, 386 A.2d 816, 825 (N.J. 1978); *Phillips v. Kimwood Mach. Co.*, 525 P.2d 1033, 1037 (Or. 1974)); *Page, supra* note 1, at 87 n.2 (“In the area of warnings, there are a handful of decisions holding that defendant might be liable for failing to warn of unknowable risks.”) (citing *Hayes v. Ariens Co.*, 462 N.E.2d 273 (Mass. 1984); *Beshada v. Johns-Manville*



## B. Comment k to the *Restatement (Second) of Torts*, § 402A

Comment k to § 402A of the Second Restatement of torts suggests one approach for avoiding liability in such situations. Comment k addresses “unavoidably unsafe products,” and it states that manufacturers, such as those of prescription drugs, are not to be held strictly liable for the “unavoidable” risks of their products.<sup>40</sup> While comment k speaks expressly to “known” risks,<sup>41</sup> as it has been adopted by courts, it promises to address some of the concerns expressed in Part I concerning liability for risks unknown to the manufacturer at the time of FDA approval.

Comment k has been adopted in a majority of jurisdictions that have considered it,<sup>42</sup> but only a minority of courts have interpreted the comment to except all prescription drugs from

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Prods. Corp., 447 A.2d 539, 547–49 (N.J. 1982)); W. Page Keeton, *Products Liability—Inadequacy of Information*, 48 TEX. L. REV. 398, 404 (1970).

<sup>40</sup> RESTATEMENT (SECOND), *supra* note 38, § 402A, comment k (1965). The comment reads, in part:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true . . . in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety . . . but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products . . . is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

*Id.*

<sup>41</sup> *Id.*

<sup>42</sup> Brown v. Superior Court, 751 P.2d 470, 476 (Cal. 1988) (citing DeLuryea v. Winthrop Labs., 697 F.2d 222, 228–29 (8th Cir. 1983); Basko v. Sterling Drug, Inc., 416 F.2d 417, 425–26 (2d Cir. 1969); Stone v. Smith, Kline & French Lab., 447 So. 2d 1301, 1303–04 (Ala. 1984); Gaston v. Hunter, 588 P.2d 326, 338–41 (Ariz. Ct. App. 1978); Chambers v. G.D. Searle & Co., 441 F. Supp. 377, 380–81 (D. Md. 1975); Johnson v. Am. Cyanamid Co., 718 P.2d 1318, 1323 (Kan. 1986)).

strict liability, granting manufacturers of prescription drugs “blanket immunity” from strict liability for injuries resulting from the design of their products.<sup>43</sup> In a frequently cited opinion, one such court has read comment k to impose liability on a drug manufacturer “only if it failed to warn of a defect of which it either knew or should have known.”<sup>44</sup> Such a test would seem to address the objections to strict liability raised in Part I, as long as courts adopted the FDA’s assessment of the value of further investigation to determine whether a manufacturer “should have known” of a risk. However, this would effectively amount to preemption or an effective

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<sup>43</sup> *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 836 (Neb. 2000) (citing *Brown v. Superior Court*, 751 P.2d 470; *Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991); *Young v. Key Pharmaceuticals*, 922 P.2d 59 (1996) (en banc)). The “blanket immunity” phrase is somewhat misleading, as courts adopting this application of comment k have excepted drug manufacturers from strict liability only to hold them liable under a negligence standard. *See infra* note 44 and accompanying text.

While only a minority of courts have read comment k to except all prescription drugs from strict liability, the majority of courts that have adopted comment k apply it on a “case-by-case basis.” *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d at 837 (citing *Tobin v. Astra Pharmaceutical Products, Inc.*, 993 F.2d 528 (6th Cir.1993); *Hill v. Searle Laboratories*, 884 F.2d 1064 (8th Cir.1989); *Castrignano v. E.R. Squibb & Sons, Inc.*, 546 A.2d 775 (R.I.1988); *Toner v. Lederle Laboratories*, 112 Idaho 328, 732 P.2d 297 (1987); *Ortho Pharmaceutical Corp. v. Heath*, 722 P.2d 410 (Colo.1986), overruled on other grounds, *Armentrout v. FMC Corp.*, 842 P.2d 175 (Colo.1992); *Feldman v. Lederle Laboratories*, 97 N.J. 429, 479 A.2d 374 (1984); *Belle Bonfils Memorial Blood Bank v. Hansen*, 665 P.2d 118 (Colo.1983) (superseded by statute in regard to blood banks, as recognized in *United Blood Services v. Quintana*, 827 P.2d 509 (Colo.1992)). These jurisdictions employ widely varying approaches to liability for prescription drugs, but “they typically balance the importance of the product’s benefit, the seriousness of the risks it presents, the societal interest in making the product available, and the enhanced accountability that applying strict liability would impose.” *Cupp, supra* note 33, at 86.

One court, for instance, allows manufacturers an affirmative defense when they show that: “(1) the product is properly manufactured and contains adequate warnings, (2) its benefits justify its risks, and (3) the product was at the time of manufacture and distribution incapable of being made more safe.” *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d at 840. In the text, I do not focus on this case-by-case approach, although it is adopted by the majority of courts, because, like the California Supreme Court, I find it unworkable for courts, *see Brown v. Superior Court*, 751 P.2d at 481–82, and particularly ill-suited to address the problems discussed in Part I of this paper. The second and third elements, in particular, would require a complete displacement of the FDA’s cost-benefit calculus, and would require an enormous investment of resources for courts to make determinations they are not well-suited to make. *See infra*, notes 45–47 and accompanying text.

<sup>44</sup> *Brown v. Superior Court*, 751 P.2d at 476.

regulatory compliance defense, and it would fail to account for manufacturers' evolving state of knowledge—as it is or as it should be—as their products are widely used over long periods of time.

Courts adopting comment k and imposing liability for injuries resulting from risks that manufacturers knew or should have known about must therefore either duplicate the work of the FDA,<sup>45</sup> potentially adopting different standards from the Agency's,<sup>46</sup> or eliminate all incentives for manufacturers to continue monitoring their drugs post-FDA approval. Both approaches are undesirable. The first option would require courts operating within the comment k framework to make their own determinations of what firms knew or ought to have known when, giving rise to precisely the problems discussed in Part I. In addition, it would engage courts in a very expensive task that they are not well-equipped to execute: determining not only whether an injury was caused by a risk created by a given prescription drug, but also whether that risk was known to the manufacturer at the time of injury and, if not, whether the risk should have been known.<sup>47</sup>

The second option would eliminate both incentives and resources for private parties to invest in post-approval risk monitoring and safety investigations. Such incentives are created when manufacturers are held liable for risks that were not apparent at the time of FDA approval. As discussed above, at the time of FDA approval, information regarding a drug's risks is

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<sup>45</sup> See Richard B. Stewart, *Regulatory Compliance Preclusion of Tort Liability: Limiting the Dual-Track System*, 88 GEORGETOWN L. J. 2176, 2178 (2000) ("Tort litigation, in practical effect, amounts to a second, duplicative system of review of the agency's decision, conducted in accordance with quite different procedures and principles.").

<sup>46</sup> See Stewart, *supra* note 45 at 2176 ("Jury nullification of regulatory risk-benefit balancing decisions can impose undue costs or otherwise restrict the use and development of socially beneficial products and processes.").

<sup>47</sup> See *infra* Part III.B. See Gillette & Krier, *supra* note 16, at 1034–35 for a summary of frequently heard arguments regarding courts' lack of fitness for this task.

incomplete.<sup>48</sup> The private investment that is motivated by holding manufacturers liable for risks discovered post-marketing not only produces information regarding previously unknown risks but sometimes alerts the FDA that there is a safety question worth pursuing, leading it to take investigatory action of its own.<sup>49</sup> To preempt all tort liability on the basis of information known at the time of FDA approval or to allow for a complete regulatory compliance defense would eliminate this valuable resource, creating a void that the FDA is not equipped to fill.<sup>50</sup>

While the FDA has in place several programs designed to monitor prescription drugs on the market,<sup>51</sup> these programs are not entirely effective.<sup>52</sup> For instance, the FDA will sometimes obtain a commitment from manufacturers that they will engage in what is known as Phase IV

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<sup>48</sup> See *supra*, notes 8–10 and accompanying text; Robert J. Temple & Martin H. Immel, *Safety of Newly Approved Drugs: Implications for Prescribing*, 287 JAMA 2273 (May 1, 2002) (“Sometimes the new information [discovered post-marketing] is so important it fundamentally changes the place of the drug in therapy . . . and sometimes the post marketing discoveries cause the drug to be withdrawn.”).

<sup>49</sup> *Wyeth*, 555 U.S. \_\_\_\_ (slip op., at 22). See also Struve, *supra* note 8, at 593 (“The filing of . . . a suit could flag possible safety problems for the FDA. Discovery obtained in such a suit might uncover evidence that had not been reported to the FDA, or upon which the FDA had not yet focused.”) For a comment on (and criticism of) the extent of discovery and its potential to uncover information relevant to a drug’s risks, see Cortese & Blaner, *supra* note 7 at 177–78.

<sup>50</sup> See Struve, *supra* note 8, at 613 (“eliminating litigation would deprive regulators of a potentially useful source of information on product safety . . . .”); Schuck, *supra* note 3, at 24. (“Professors Robert Rabin and Richard Nagareda mention “information updating” concerning drug-related risks as a putative benefit of tort litigation. This benefit is especially important to the extent that the FDA fails to effectively monitor post-approval risk information and incorporate that information into its labeling and other regulatory decisions.”) See also Nagareda, *supra* note 10, at 5–6; Robert L. Rabin, *Keynote Paper: Reassessing Regulatory Compliance*, 88 Geo. L.J. 2049, 2068–70 (2000).

<sup>51</sup> See TASK FORCE ON RISK MANAGEMENT, *supra* note 11, at 54–63 for a discussion of the FDA programs in place for assessing risk post-marketing.

<sup>52</sup> See generally FDA SCIENCE BOARD, REPORT OF THE SUBCOMMITTEE ON SCIENCE AND TECHNOLOGY: FDA SCIENCE AND MISSION AT RISK 2, 6 (2007), available at [http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b\\_02\\_01\\_FDA%20Report%20on%20Science%20and%20Technology.pdf](http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf); NATIONAL ACADEMIES, INSTITUTE OF MEDICINE, THE FUTURE OF DRUG SAFETY: PROMOTING AND PROTECTING THE HEALTH OF THE PUBLIC 193–194 (2007); GAO, DRUG SAFETY: IMPROVEMENT NEEDED IN FDA’S POSTMARKET DECISION-MAKING AND OVERSIGHT PROCESS 5 (GAO–06– 402, 2006), <http://www.gao.gov/new.items/d06402.pdf>.

testing: post-approval studies into a drug’s safety and effectiveness.<sup>53</sup> But usually when the FDA extracts such promises from manufacturers “[t]here is little or no discussion about the matter between the applicant and FDA personnel, and virtually no supervision or attempt at consistent policy. . . .”<sup>54</sup> As a result, Phase IV tests that are supposedly required are often irrelevant, never completed, or never reviewed by the FDA.<sup>55</sup>

Similarly, the FDA requires manufacturers to report to the FDA any adverse events that have been found “associated” with their products.<sup>56</sup> However, both the healthcare community and the FDA have noted shortcomings in the FDA’s ability to collect, analyze, and appropriately respond to the vast amounts of information such a system produces, including hundreds of thousands of reports per year.<sup>57</sup> A simple shortage of resources prevents the FDA from, among other things, engaging in research designed to determine the causality of drug-related injuries and trolling reported adverse effects for “signals” of potential safety problems.<sup>58</sup> The promise of tort recoveries can motivate plaintiffs’ attorneys to invest resources in filling some of these post-marketing monitoring gaps,<sup>59</sup> and, properly designed, a system of liability might motivate

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<sup>53</sup> HUTT, ET AL., *supra* note 8, at 727.

<sup>54</sup> *Id.*

<sup>55</sup> *Id.* at 727–28, 738 (citing OFFICE OF INSPECTOR GENERAL, FDA’S MONITORING OF POSTMARKETING STUDY COMMITMENTS, OIG REP. No. OEI–01–04–0039 (June 2006)).

<sup>56</sup> 21 C.F.R. 314.80.

<sup>57</sup> TASK FORCE ON RISK MANAGEMENT, *supra* note 11, at 53, 54. “Despite the number and variety of postmarketing risk assessment programs that FDA has initiated, the changing healthcare environment is challenging the Agency’s efforts to rapidly identify, quantitate, and understand new risks associated with marketed products . . . . [R]esources have not permitted . . . desired enhancements.” *Id.* at 65.

<sup>58</sup> *Id.* at 67.

<sup>59</sup> Peter Schuck dismisses this argument on the grounds that “it would be surprising indeed if lay plaintiffs’ lawyers originated this information—as distinguished from marshalling and shaping information unearthed by others into more focused, tendentious forms for litigation purposes.” SCHUCK, *supra* note 3, at 25. However, the FDA Task Force on Risk Management’s report indicates that marshalling and shaping information are precisely the tasks with which the

manufacturers to engage in post-marketing monitoring of their own products.<sup>60</sup>

However, even with the threat of liability, as long as liability turns on a showing of both causation and knowledge, as required where comment k has been applied, firms have a incentive not to investigate the adverse effects of their drugs.<sup>61</sup> Various proposals have been put forward for overcoming this disincentive. Some observers have suggested that courts shift the burden of proof to the manufacturer whenever general causation is uncertain.<sup>62</sup> However, this would simply exacerbate the problems discussed in Part I, as it assumes that wherever there is uncertainty about a product's risks, that product should not be marketed.<sup>63</sup> Such an approach would undermine any determination by the FDA that the benefits of a drug's availability outweighed any anticipated benefits of further pre-market inquiry.<sup>64</sup>

Peter Schuck suggests that manufacturers can be incentivized to “gather, analyze, and disclose all relevant risk information to the FDA, Congress, and the public in a timely fashion” with liability rules that except from FDA preemption of state tort claims and from any state law regulatory compliance defense “cases in which the manufacturer fraudulently withholds from the agency regulation-relevant risk information.”<sup>65</sup> However, it is hard to see how such an exception

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FDA can use the most assistance. *See* TASK FORCE ON RISK MANAGEMENT *supra* note 11, at 53–54 and accompanying text.

<sup>60</sup> *See* Struve, *supra* note 8, at 612 (“A regulatory compliance defense would remove a company’s incentive to work proactively to address emerging safety issues. . .”).

<sup>61</sup> *See* Rebecca S. Dresser, et al., *Breast Implants Revisited: Beyond Science on Trial*, 1997 WIS. L. REV. 705; Feldman, *supra* note 22.

<sup>62</sup> Dresser, et al., *supra* note 58; Feldman, *supra* note 22.

<sup>63</sup> *See* Feldman, *supra* note 22, at 45 (“[R]epeatedly absolving defendants of liability in the face of strong uncertainty encourages defendants to market their products before they have extensive information about the causal powers of their goods.”).

<sup>64</sup> *See supra* notes 9–20 and accompanying text.

<sup>65</sup> SCHUCK, *supra* note 3, at 10. *See also* AMERICAN LAW INSTITUTE, REPORTER’S STUDY, ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY (1991) [hereinafter “ALI REPORTER’S STUDY”] (proposing preclusion of tort liability where a risk “been placed under regulatory control by a specialized administrative agency”; the defendant has complied with all regulatory

would motivate a firm to engage in on-going research about its product's safety beyond the minimum expressly demanded by the FDA. Providing manufacturers with an incentive to engage in post-market monitoring of their products' risks should be a primary goal of any tort or administrative plan for addressing the risks of prescription drugs.<sup>66</sup>

### **III. An ideal negligence approach and its shortcomings as applied by courts.**

Unlike most products, prescriptions drugs are kept off the market unless and until a government agency determines that the social benefits of marketing outweigh the risks.<sup>67</sup> In theory then, tort liability is not needed to incentivize manufacturers to perform the same calculus before marketing. However, some form of post-approval monitoring is needed to ensure that manufacturers continue to market prescription drugs only when to do so is socially beneficial.<sup>68</sup> This is true for at least two reasons.

First, as discussed in Part II, the agency has insufficient resources to develop, collect, and analyze information post-marketing. Furthermore, in the absence of an effective regulatory or liability system, private parties lack incentives to report adverse effects,<sup>69</sup> and manufacturers

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requirements; and the defendant has disclosed to the agency all material information); Stewart, *supra* note 43 (endorsing the ALI REPORTER'S STUDY proposals).

<sup>66</sup> See Dresser et al., *supra* note 62, at 731 (“[W]hen . . . good science is missing, shouldn't the legal system also consider why it is missing, who is best situated to produce it, and how it ought to be undertaken?”)

<sup>67</sup> See *supra*, note 4 and accompanying text; *supra* notes 8–15 and accompanying text.

<sup>68</sup> Cf. Page, *supra* note 1, at 128 (“There still will be instances, however, where society would have been better off if defendant had refrained from putting a product on the market, and damage suits using negligence doctrine would usefully complement the legislative and administrative processes as mechanisms to protect the public from the unavoidable hazards posed by these consumer goods.”).

<sup>69</sup> Dresser et al., *supra* note 62, at 723, 732 n. 62 (“It is generally believed that U.S. physicians significantly underreport to the FDA adverse events involving drugs and devices, because of unfamiliarity with the reporting system, ‘complacency’ regarding drug and device

have every incentive to drag their feet in presenting the FDA with adverse information or investing in research to uncover potential adverse effects.<sup>70</sup> Therefore, some form of post-approval monitoring is necessary to ensure that manufacturers' decision to market is socially beneficial not just at the time of FDA approval, but as time passes and more risks become known.

Second, in addition to the FDA's inability to monitor post-marketing risks sufficiently, the FDA sometimes makes mistakes when it approves drugs in the first instance. These mistakes might result from errors committed by the FDA,<sup>71</sup> or from manufacturers' failure to share all relevant information with the FDA during the investigational phases.<sup>72</sup>

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safety, liability implications of acknowledging problems, feelings of culpability about patients' problems, and causation questions.") (citing American Medical Association, *Reporting Adverse Drug and Medical Device Events: Report of the AMA's Council on Ethical and Judicial Affairs*, 49 FOOD & DRUG L. J. 359, 361 (1994)).

<sup>70</sup> See *supra* notes 48–66 and accompanying text.

<sup>71</sup> Such errors might be the result of poor judgment, see Merrill, *supra* note 8, at 16, or of "administrative laxity" or "carelessness," *id.* at 20–22 (providing as an example evidence of carelessness, such as the Agency's failure to follow-up on doubts expressed by experts, during the pre-market investigation of the drug Orabio). See also Dresser et al., *supra* note 62, at 707 (attributing the "silicone gel breast implant controversy [to] manufacturers, physicians, and federal officials [who] allowed the devices to be used without adequate safety data [and] the failure to conduct adequate research during the early stages of implant development and use").

They might also be attributed to "agency capture." For a discussion of factors that might lead us to suspect agency capture is a problem, see Gillette & Krier, *supra* note 16, at 1064–69. See also Feldman, *supra* note 22 (attributing errors arising from lax agency oversight to "the financial incentives for drug companies to hurry new drugs to market in a relatively weak administrative-regulatory environment").

<sup>72</sup> Feldman, *supra* note 22, at 20, 22–23 (discussing manufacturer "duplicitous" and providing as an example Richardson-Merrell's criminal withholding of relevant test results pending FDA determination of whether to approve its cholesterol drug MER/29). See also Dresser et al., *supra* note 62, at 732–33 (identifying several toxic tort litigations, some involving prescription drugs such as Bendectin, that involved "manufacturers who inadequately tested the long-term safety of products or who concealed adverse results while continuing to market the product after the testing was done").

While some instances of withheld information are blatant, there are other, less obviously sinister reasons why the FDA may be operating with less information than the manufacturer. After all, the manufacturer and not the FDA performs all clinical trials and then provides FDA



Some post-marketing process is necessary to account for these failings, and to ensure that manufacturers are not marketing products when the benefits of doing so do not outweigh the costs. As discussed in Part I, such a system must avoid undermining any informed decision made by the FDA regarding the desirability of marketing at a given time, and it must keep in mind the relative capacities of all relevant institutions, including government agencies, courts, and private parties.

In this Part, I will draw from proposals for holding prescription drug manufacturers liable in tort when the benefits of their products do not outweigh their costs. I will argue that while these negligence approaches in theory address the concerns I have identified regarding the need to establish appropriate incentives for manufacturers, they are insufficiently cognizant of courts' strengths and limitations. Applied in the courtroom, they would serve to distort manufacturers' incentives, and to do so at great expense. In Part IV, I will therefore propose a regulatory approach that would allow the FDA to perform and oversee those aspects of product evaluation that courts are particularly ill-suited to perform. This approach, however, would retain those aspects of the current liability system that incentivize private actors—both plaintiffs' attorneys and manufacturers—to invest in ongoing monitoring activity.<sup>73</sup>

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with the information. *See, e.g.,* Merrill, *supra* note 8, at 17; Gillette & Krier, *supra* note 16, at 1068 n. 111 (noting that agencies rely on information largely supplied by the regulated industry); SCHUCK, *supra* note 3, at 27 (observing, “first, that manufacturers and other regulated entities have much better and cheaper access to risk information than the FDA in the first instance; second that the FDA depends on this information for optimal safety regulation; and third, that the regulatory standard might have been different (usually more stringent) had the FDA been so informed”). Peter Schuck identifies three kinds of “disclosure deficits” in addition to those caused by firms’ intentional misrepresentations : “(1) negligent misrepresentation, (2) innocent misrepresentation, and (3) failure (not amounting to an affirmative misrepresentation) to inform the agency in a timely fashion about material risk relevant information.” *Id.* at 29

<sup>73</sup> Providing sufficient incentives to motivate private involvement is important not only to ensure that sufficient private resources are devoted to investigation and monitoring in order to make up for public resource deficiencies, but also to counter some concerns about agency

### A. A negligence model.

The concerns addressed in Parts I and II of this paper would, in an ideal system, be addressed by adopting a version of negligence liability, combined with a limited form of regulatory preemption that would allow appropriate agency determinations to define the extent of manufacturers' knowledge. Such an approach is largely captured in the Third Restatement of torts' treatment of prescription drugs.<sup>74</sup>

The Third Restatement devotes an entire section to prescription drugs and medical devices,<sup>75</sup> and it states that a prescription drug manufacturer is liable for harm only when such harm is caused by a "defect" in the drug.<sup>76</sup> A defect occurs when the drug "is not reasonably safe due to defective design,"<sup>77</sup> which, in turn, occurs when "the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients."<sup>78</sup>

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capture, as well as concerns about individuals' access to agencies. See Gillette & Krier, *supra* note 16, at 1064-70. See also David Rosenberg & James P. Sullivan, *Coordinating Private Class Action and Public Agency Enforcement of Antitrust Law*, 2(2) JOURNAL OF COMPETITION LAW AND ECONOMICS, 159, 160-61, 167-68 (May 4, 2006) (identifying private enforcers as "a hedge against the potential (real or perceived) for under-enforcement by public agencies vulnerable to bureaucratic slack and stagnation, political and personal conflicts of interest, and chronic under-funding"); Cheng, *Changing Scientific Evidence*, 88 MINN. L. REV. 315, 336-337 (2003).

<sup>74</sup> RESTATEMENT (THIRD), *supra* note 21, § 6.

<sup>75</sup> *Id.*, § 6.

<sup>76</sup> *Id.*, § 6(a).

<sup>77</sup> *Id.*, § 6(b)(2). Manufacturers under the Third Restatement can also be held liable for manufacturing defects, *id.*, § 6(b)(1), and for failures to warn, *id.*, § 6(b)(3), which occur "if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to [health-providers under certain circumstances or patients under others]," *id.*, § 6(d).

<sup>78</sup> *Id.*, § 6(c). The drafters explain:

This particular weighing of costs and benefits—which deems a drug non-defective whenever it is more beneficial than harmful “to any class of patients”—might be criticized as the improper metric for calculating social value.<sup>79</sup> However, I do not cite it here to emphasize its particular approach to weighing costs and benefits. Rather, I mean to highlight it as a proposal for a negligence-based liability approach. Under the Third Restatement, liability for prescription drug injuries turns on the social value of the drug, given its benefits and costs to society as a whole, as they were known or should have been known at the time of marketing. This is essentially a negligence approach, although it is not presented in those terms.<sup>80</sup>

A central element of a negligence approach such as that encapsulated in the Third Restatement, § 6, is determining what the manufacturer knew or should have known regarding its product’s risks, which in turn requires an assessment of how much inquiry into such risks a manufacturer should have conducted before marketing.<sup>81</sup> A negligence approach like the one highlighted here therefore directly implicates the concerns discussed above about inducing a suboptimal level of avoidance in manufacturers, which may be incentivized by the threat of tort

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Under Subsection (c), a drug is defectively designed only when it provides no net benefit to any class of patients. Courts have concluded that as long as a drug or medical device provides net benefits to some persons under some circumstances, the drug or device manufacturer should be required to instruct and warn health-care providers of the foreseeable risks and benefits.”

*Id.*, § 6, comment b.

<sup>79</sup> *See, e.g.*, *Freeman v. Hoffman-LaRoche, Inc.*, 618 N.W.2d 827, 840 (Neb. 2000) (rejecting § 6(c) as having “no basis in the case law” and as being “too strict a rule”).

<sup>80</sup> John Vargo, *Caveat Emptor: Will the A.L.I. Erode Strict Liability in the Restatement (Third) for Products Liability*, 10 *TOURO L. REV.* 21, 23 (1993) (describing the Third Restatement’s approach as “simply a return to negligence”). *Cf.* Page, *supra* note 1 (promoting a negligence approach that, like the Third Restatement, would hold manufacturer’s liable based on their decision to market products with social risks outweighing their social benefits).

<sup>81</sup> *Cf.* *Gober v. Revlon, Inc.*, 317 F.2d 47, 51 (treating as a central element of a negligence suit the claim that the defendant “should have known that the tests which it conducted with respect to [its product] were not adequate to disclose the possibility of injurious reaction”).

liability to engage in more pre-marketing investigation than has been deemed socially optimal by the FDA.<sup>82</sup>

In response to this concern,<sup>83</sup> the Third Restatement hints at a limited regulatory compliance defense, “recogniz[ing] that the regulatory system governing prescription drugs is a legitimate mechanism for setting the standards for drug design.”<sup>84</sup> Such preemption is found under the Third Restatement only in limited circumstances:

when the safety statute or regulation was promulgated recently, thus supplying currency to the standard therein established; when the specific standard addresses the very issue of product design or warning presented in the case before the court; and when the court is confident that the deliberative process by which the safety standard was established was full, fair, and thorough and reflected substantial expertise.<sup>85</sup>

In other words, the Third Restatement encourages courts to defer to agency determinations of a drug’s marketability, but it implicitly recognizes the dangers of accepting a regulatory compliance defense when the underlying agency determination was based on incomplete or out of date information or was otherwise incomplete.<sup>86</sup>

In theory, these two elements—a negligence approach turning on the social value of marketing a particular drug, and deference to on-point and reliable agency determinations of

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<sup>82</sup> See *supra* Part I. Cf. DAVID ROSENBERG & CHARLES FRIED, MAKING TORT LAW: WHAT SHOULD BE DONE AND WHO SHOULD DO IT, 85 (2003) (“Assuming that the agency’s regulation does not merely set the lower bound on acceptable safety measures, the added burden of threatened liability in tort could induce firms to overinvest in precautions, especially in excessive reduction of activity level.”)

<sup>83</sup> See RESTATEMENT (THIRD), *supra* note 21, § 6, comment b (expressing “concerns over the possible negative effects of judicially imposed liability on the cost and availability of valuable medical technology”).

<sup>84</sup> RESTATEMENT (THIRD), *supra* note 21, § 6, comment b.

<sup>85</sup> RESTATEMENT (THIRD), *supra* note 21, § 4, comment e. This approach closely echoes that of an earlier American Law Institute report. See ALI REPORTER’S STUDY, *supra* note 65 (proposing preclusion of tort liability under nearly identical circumstances); Stewart, *supra* note 45 (endorsing the ALI REPORTER’S STUDY proposals).

<sup>86</sup> See *supra* notes 48–58 and accompanying text.

whether the activity in question is socially desirable—should successfully meet the challenges outlined above in Parts I and II. On the one hand, such an approach would adhere to the level of knowledge imputed to the manufacturer by the FDA and so would avoid incentivizing manufacturers to over-invest in pre-market investigation and risk-avoidance.<sup>87</sup> On the other, it would recognize the time-bound nature and potential weaknesses of such agency determinations.<sup>88</sup>

Where further information showed the FDA's initial weighing of costs and benefits no longer to apply, under this approach, the decisionmaker would determine, as the FDA did in the first instance, what level of knowledge was optimal to impute to the manufacturer and, given that level of knowledge, whether marketing of the product was and continues to be on the whole socially beneficial. If accurately applied, such an approach would incentivize manufacturers to engage in an optimal level of post-market monitoring.<sup>89</sup> The approach calls for assessing what level of information manufacturers should have attained, and it holds manufacturers liable only to the extent that they failed to act on information they should have known. Under such a

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<sup>87</sup> See *supra* notes 8–20 and accompanying text.

<sup>88</sup> See *supra* notes 48–58 and accompanying text.

<sup>89</sup> In theory, a negligence approach such as the one outlined here, by imputing knowledge to manufacturers, would overcome the usual incentives created by a negligent standard of liability for manufacturers to avoid acquiring information about the risks associated with their products. As Heidi Li Feldman has observed:

[P]lacing the burden of proof on the plaintiff creates a perverse incentive for actors to foster strong uncertainty about general causation, so as to escape liability . . . . In other words, the current system, rather than motivating actors to acquire sufficient information so as to align their estimations of risk with the actual causal impact their products or conduct will have, motivates actors to acquire only enough information about the causal powers of their products or conduct to be able to demonstrate strong uncertainty in the event of litigation.

Feldman, *supra* note 22, at 41. However, where not only the level of information the manufacturer possesses, but the level of information the manufacturer should possess, are examined and open a manufacturer to liability, such incentives are reversed.

system, manufacturers would have an incentive to obtain the appropriate amount of information.<sup>90</sup>

However, while an approach like that suggested by the Third Restatement is, in theory, ideal, in practice it is a thoroughly impractical and probably impossible approach for courts to adopt, given their institutional competencies and limitations. Should they attempt to adopt such an approach, results would be haphazard and misdirected, and would fail to incentivize the optimal levels of caution and activity hoped for.

### **B. Courts' institutional limitations.**

Courts are particularly ill-suited to engage in the types of analysis discussed in Part III.A. When faced with a claim for damages allegedly caused by a prescription drug, courts applying an approach like that outlined above would be required to: (1) determine whether the FDA had addressed the specific harm at issue, and if so (2) determine whether the FDA was acting on accurate information, and if so (3) determine whether more up-to-date information had rendered the FDA's determination obsolete, and given that new information, (4) determine whether the manufacturer should have known of additional risks not considered by the FDA or misestimated by the FDA, and if so (5) determine, given all information concerning the drug's risk's and benefits, and the nature of the drug's possible but unknown risks, whether the drug's availability on the market should be deemed socially beneficial. In addition, the court would need to determine both general causation—whether the drug presents the type of risk alleged to have caused the plaintiff injury—and specific causation—whether the plaintiff's particular injury was

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<sup>90</sup> Of course, this rests on the assumption that manufacturers can accurately predict what level of knowledge will be imputed to them or, in other words, what level of monitoring is expected. See *infra* notes 106–107 and accompanying text for a discussion of courts' inability to provide such predictability.

caused by the drug. Courts are not well equipped to engage in such a project.<sup>91</sup>

Many scholars have noted courts' deficiencies in grappling with highly scientific questions and those that require a broad assessment of an activity's social benefits and costs. Even with regard to determinations of causation—determinations that are at the core of courts' province—when it comes to injuries alleged to have been caused by prescription drugs, courts are not ideal institutions for settling questions of causation. Two types of causation questions arise in prescription drug cases, those of specific and those of general causation.<sup>92</sup>

While scholars and courts have come up with statistical and other mathematical approaches for approaching questions of specific causation,<sup>93</sup> determining general causation might pose an even larger challenge. In many cases, scientists are simply uncertain with regard to whether a certain drug poses an alleged risk.<sup>94</sup> As many scholars have observed, courts' determinations of liability traditionally turn on conclusive determinations of causation.<sup>95</sup> Where a manufacturer has caused injury, it may be held liable; where it has not, it cannot. Unlike agency processes, courts' one-off encounters with individual plaintiffs alleging injury from

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<sup>91</sup> In addition to the difficulties of having courts answer such complex, technical, and value-laden questions, courts are not well-equipped to react should a determination be made that, given the state of imputed knowledge about a drug, marketing may still be socially beneficial, but further investigation is warranted.

<sup>92</sup> Cheng, *supra* note 73, at 319.

<sup>93</sup> See, e.g. Troyen A. Brennan, *Causal Chains and Statistical Links: The Role of Scientific Uncertainty in Hazardous-Substance Litigation*, 73 CORNELL L. REV., 469, 509 (1988) (explaining approaches based on “statistical models and mathematical formulae” to determine causation).

<sup>94</sup> Cheng, *supra* note 73, at 320 (“[T]here may be uncertainty about the calculation of risk itself.”); Feldman, *supra* note 22, at 32 (“Scientists’ genuine uncertainty renders it a matter of luck whether the jury answers the question correctly.”);

<sup>95</sup> See Cheng, *supra* note 73, at 320 (“Many toxic tort cases are brought when a mature scientific record has not yet developed: The law wants answers, but science is not ready.”); Feldman, *supra* note 22, at 42 (arguing that conclusiveness is necessary in tort litigation, but it creates a false construct with no corresponding value in the scientific world); Dresser, *supra* note 62.

specific risks require yes-or-no final determinations; they are not designed to accommodate changing scientific knowledge.<sup>96</sup> The ideal inquiry outlined in Part II.A. must be able to accommodate such uncertainty and development, and must sometimes be able to defer final determinations until greater information is known.

In addition, the global weighing of costs and benefits presented by a prescription drug is not a task that courts can complete with ease, not only because it rests on complex and technical determinations of fact,<sup>97</sup> but because it requires political judgments about the relative weights of costs and benefits that a drug creates for society as a whole, and not just for the parties at issue in a given litigation.<sup>98</sup> This is due, at least in part, to the case-by-case and fact-specific manner in which judges and juries arrive at their determinations.<sup>99</sup> Furthermore, as Peter Huber has argued extensively, judges and juries cannot always be trusted to give sober consideration to the general risks and benefits of a technologically complex product when faced with the dramatic facts of a

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<sup>96</sup> See Feldman, *supra* note 22, at 47 (“[A]n administrative scheme holds some attractiveness because by abandoning tort’s expressive goal and transforming its allocative one, this kind of program minimizes the significance of certainty about causation.”).

<sup>97</sup> See SCHUCK, *supra* note 3, at 19 (arguing with regard to jury strengths that “the ability to process detailed scientific research information and complex risk-risk tradeoffs, and to make or second-guess technocratic decisions about drug design and labeling, is not among them”); Stewart, *supra* note 45, at 2176 (noting the tort system’s “record of error in resolving scientifically and technically complex issues”); *Bradley v. Weinberger*, 483 F.2d 410 (1st Cir. 1973) (“Courts are not best equipped . . . to judge the merits of the scientific studies and the objections to them. Specialized agencies like the FDA are created to serve that function.”).

<sup>98</sup> See Stewart, *supra* note 45, at 106 (“Judgments about whether the choice to market a type of product was reasonable require a weighing of societal risks and benefits, a responsibility that should be the exclusive province of the legislative branch.”).

<sup>99</sup> See SCHUCK, *supra* note 3, at 19 (noting that juries do not have the opportunity to “learn from [their] environment and correct [their] policy mistakes in a timely fashion,” given the “incremental[ and] ad hoc” nature of common law development, which makes “generalization and rationalization . . . possible only after a significant number of fact-specific adjudications accumulate”).



particular plaintiffs' case.<sup>100</sup>

As Huber goes on to observe, judge and jury determinations regarding the net social value of a product like a prescription drug are likely to be not only unwise,<sup>101</sup> but inconsistent.<sup>102</sup> This is troubling for two reasons. First, it suggests that the outcomes of litigation involving injuries alleged to have been caused by prescription drugs are sometimes wrong, a suggestion only reinforced by the fact that these outcomes rest on determinations of complex and often unsettled questions of causation.<sup>103</sup> Such misguided decisions have enormous consequences, not only for the manufacturers of the drugs in question, but for society as a whole. Frequently, when a court finds that a drug caused an alleged harm, manufacturers must respond by withdrawing the product from the market, dramatically raise prices, or even declare bankruptcy.<sup>104</sup> Court errors that have the capacity to drive products or even firms out of the marketplace make drugs that the FDA has deemed, or would have deemed, socially beneficial unavailable.<sup>105</sup>

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<sup>100</sup> See, e.g., Huber, *Safety and the Second Best*, *supra* note 2, at 320 ("The courts, like so many legal commentators, are almost certain to adopt a simplistic, disease-specific focus on risk while entirely ignoring the collateral, risk-reducing benefits that attend almost every mass-produced or technologically-innovate good or service."). See also Gillette and Krier, *supra* note 16, at 1035 (summarizing arguments against the competence of judges and juries with regard to "public risk assessment and management").

<sup>101</sup> Gillette and Krier, *supra* note 16, at 319 ("[J]udges and juries have little capacity to make risk choices wisely.").

<sup>102</sup> *Id.* at 319–320.

<sup>103</sup> See *supra*, notes 93–96 and accompanying text.

<sup>104</sup> Schwartz & Goldberg, *supra* note 10, at 165 (citing as examples of "bad courtroom decision-making" that led to such outcomes "cases involving Bendectin, breast implants, and certain vaccines"). See also Cheng, *supra* note 73, at 323–323 ("[W]hen the stakes are high, errors cause widespread social and economic harm. . . . The fear of future litigation will cause some manufacturers to exit the market and deter others from entering it in the first place.").

<sup>105</sup> Some experts have observed:

In recent years, it has no longer been necessary for FDA to take legal action to remove an unsafe drug from the market. As soon as serious toxicity is encountered—often discovered by the company rather than by FDA—the manufacturer will voluntarily remove the product from the market as quickly as

Second, inconsistent decisions undermine the effort to set a clear standard of expected behavior for manufacturers and distort their marketing and research incentives. A primary goal of the system described in Part III.A was to provide manufacturers with an incentive to engage in socially beneficial levels of product investigation, monitoring, and marketing.<sup>106</sup> Where courts are unable to provide clear signals regarding what those levels are, manufacturers are likely to respond with suboptimally high levels of care and insufficient activity.<sup>107</sup>

#### **IV. A regulatory alternative to tort liability for the ongoing monitoring of risk.**

Given courts' deficiencies in the areas described above, the project of ongoing risk assessment and evaluation should be carried out within the Food and Drug Administration. The Agency should become responsible for determinations of causation,<sup>108</sup> as well as for weighing costs and benefits to assess a product's net utility to society. The FDA is clearly more suited to these types of inquiry, as they are precisely tasks the FDA most frequently performs as it

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possible to avoid, or at least reduce, product liability exposure. Often these drugs are effective, and in some people they are uniquely effective. FDA has frequently requested that companies continue to serve unmet medical needs with these drugs on a compassionate IND basis, but companies are reluctant to do so.

HUTT, ET AL., *supra* note 8, at 742. For example, after Vioxx was removed from the market by its manufacturer, Merck, due to liability concerns, an FDA Advisory Committee voted to bring it back. *Id.*, at 753–54. *Cf.* Cheng, *supra* note 73, at 316 (noting that, even as the FDA was determining that more research was needed to assess the safety of silicone breast implants and taking steps to initiate that research, multi-million dollar verdicts were issuing against their manufacturers).

<sup>106</sup> See *supra* note 90 and accompanying text.

<sup>107</sup> See Huber, *Saftey and the Second Best*, *supra* note 2, at 320 (“It is plain that random regulation entails social costs without commensurate benefits, and . . . novelty and mass production represent risk solutions much more often than they represent risk problems.”); Feldman, *supra* note 22, at 40 (noting that uncertainty within the tort system “makes it impossible to accomplish tort law’s goals reliably”).

<sup>108</sup> See Struve, *supra* note 8 (arguing that courts in the process of litigation should refer questions of product safety and causation to the FDA for determination).

evaluates drugs pre-marketing.<sup>109</sup> Furthermore, the Agency has plenty of post-marketing Agency and Congressional evaluation models to borrow from—a number of times Congress or the FDA has enlisted the assistance of scientific advisory boards.<sup>110</sup>

The agency’s best model, however, might be an approach taken by a federal district judge in a silicone breast implant multi-district litigation. Chief Judge Sam C. Pointer, Jr. of the U.S. District Court of Northern Alabama appointed a panel of four neutral scientists to determine whether silicone breast implants cause chronic disease.<sup>111</sup> After full discovery, Judge Pointer allowed the plaintiff and defense witnesses to present their evidence to, and be questioned by, members of the panel.<sup>112</sup> The FDA might similarly allow a private party (a “finder”) to initiate an action analogous to a tort suit. Both parties would be permitted discovery, and their evidence would be presented to a board of experts, rather than to a judge. Unlike the plaintiffs’ attorney in a tort suit, however, the finder would not be tied to a particular plaintiff or set of plaintiffs, but would be free to identify for the Agency whatever risks or injuries it suspected a prescription drug presented. Similarly, the agency investigation would not be limited to causation in a specific instance, but would incorporate all relevant risk information brought to its attention.

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<sup>109</sup> See *supra*, notes 4, 8–15 and accompanying text.

<sup>110</sup> See, e.g. HUTT, ET AL., *supra* note 8, at 580 (describing the process by which the FDA along with the National Academy of Sciences—National Research Counsel (NAS-NRC) reviewed all pre-1962 NDAs for compliance with the 1962 food and drug regulations) (citing 31 Fed. Reg. 9425 (July 9, 1966), 31 Fed. Reg. 13014 (Oct. 6, 1966), 40 Fed. Reg. 28587 (July 7, 1975)); HUTT, ET AL., *supra* note 8, at 501 (describing FDA and NIH review of an NIH study of oral hypoglycemic drugs); *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645 (1973) (discussing NAS-NRC review of evidence of the drug Bentex’s effectiveness); “Drug Safety,” Hearings Before the Intergovernmental Relations Subcommittee of the House Committee on Government Operations, 89th Congress, 1st Session (1965) (statement of Joseph F. Sadusk, Jr.) (discussing FDA’s post-approval investigation of Parnate). See also Dresser, et al., *supra* note 62, at 773–74 (“A number of scientific advisory panels have been created by Congress to assist regulatory agencies in their decisionmaking.”).

<sup>111</sup> Olivia Judson, *Slide-Rule Justice*, NAT’L J., Oct. 9, 1999, at 2882.

<sup>112</sup> *Id.*

The board and the Agency's task in each case would be as described in Part II.A above: to determine, first, what level of investigation is socially optimal, and second, given that level of knowledge, whether and under what conditions continued marketing of the manufacturer's product is socially beneficial.<sup>113</sup> The FDA, therefore, would determine the degree of investigation the inquiry merited, given the evidence supplied by both parties, and, ultimately, whether the product should remain on the market with modification, such as altered warnings; be removed from the market; or continue to be marketed without change.<sup>114</sup>

As the FDA does not have sufficient resources to carry out full-scale monitoring of prescription drugs, particularly once they have been approved for marketing,<sup>115</sup> the Agency must harness the private resources that currently fuel the current tort system.<sup>116</sup> Like the tort system, a replacement regulatory system should be driven not only by agency-initiated investigations, but by investigations demanded by private parties (i.e., the equivalent of plaintiffs' attorneys), who should be motivated to investigate possible previously unrealized risks and bring the evidence they uncover to the FDA's attention.<sup>117</sup> Furthermore, this regulatory approach must provide

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<sup>113</sup> In this way, the approach would mirror all post-marketing investigations conducted by the FDA. *See, e.g.,* Friedman, *supra* note 5, at 1728–29 (providing examples of FDA investigations into various drugs, and their subsequent removal from the market).

<sup>114</sup> *See* Merrill, *supra* note 8, at 15–16 (“The discovery of [a] substantial . . . risk after the marketing of a drug would ordinarily cause the FDA to revoke or at least revise its original judgment and the terms of its approval . . . However, there are cases in which the agency could properly permit the drug to remain on the market with its labeling unchanged).

<sup>115</sup> *See supra* notes 51–58 and accompanying text.

<sup>116</sup> *See* Cheng, *supra* note 73, at 339 (“[T]o the extent that they can aggregate individual claims and exploit the resulting economies of scale, plaintiffs' attorneys have significant incentives to sponsor research, though those incentives are only a fraction (i.e., the contingency fee percentage) of defendant incentives.”) (citing FRIED & ROSENBERG, *supra* note 102, at 88–92).

<sup>117</sup> This is a more efficient and meaningful method of bringing information to the FDA's attention than leaving the agency to sort through the vast amounts of raw data the agency collects. *Cf.* Nagareda, *supra* note 10, at 333–34 (discussing investigation into silicone implants). In addition, by providing for private parties to spur agency action, this mechanism would counter

incentives for manufacturers to invest in their own ongoing monitoring programs at the most socially beneficial levels, make such information available to the FDA, and take appropriate action in response to the information they discover.

These incentives might be provided, in small part, by a cost-shifting mechanism. If the agency determines that the information provided by the finder is worth pursuing, it might require the manufacturer to reimburse the finder for its information-generating costs, including “attorneys fees.” Should the FDA determine that further investigation was warranted, the manufacturer might be required to fund them. These combined costs would create an incentive for manufacturers to conduct research independently and to make all risk information publicly available if to do so would be less expensive than to wait for private and agency action.

However, this cost-shifting mechanism would likely not be sufficient either to motivate manufacturers to uncover information that might lead to the revocation of its product’s NDA,<sup>118</sup> or to motivate private parties to invest significant amounts of resources in potentially dead-end possibilities. Instead, in order to supply the appropriate incentives, some aspects of the current tort system should be preserved to provide, on the one hand, a penalty for manufacturers that fail to conduct appropriate levels of research of their own initiative and react accordingly, and a reward for finders that uncover significant information altering the FDA’s cost-benefit analysis regarding a particular drug.

In order to achieve these objectives, tort liability might be retained in certain circumstances, and a finder that brought the relevant information to the agency might receive exclusive right to bring a tort suit on the basis of that information. However, as with the FDA’s

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concerns about agency capture, as well as concerns about individuals’ access to agencies. *See* Gillette & Krier, *supra* note 16, at 1064-1070 (1990). *See also* Rosenberg & Sullivan, *supra* note 73, at 160–61; 167–68; Cheng, *supra* note 73, at 336-337.

<sup>118</sup> This is particularly true in light of manufacturers’ chances of escaping detection.

initial approval decision, tort liability should not be allowed to undermine any post-marketing, post-investigation determination made by the FDA regarding the utility of further investigations and the utility of having a drug available on the market. Therefore, the FDA might authorize the finder to sue in tort only where it determined that information revealed during the investigation merited an alteration in the drug's treatment, whether a change in labeling or revocation of the NDA.<sup>119</sup>

In order to identify the relevant class of injuries with regard to which the finder would be authorized to bring suit, the FDA might identify failures on the part of the manufacturer to conduct optimal research. For instance, a manufacturer might have been asked pre-approval to conduct a Phase IV study post-marketing but failed to do so,<sup>120</sup> and the study would have revealed the harm now discovered; or the advisory panel might determine that the manufacturer should have engaged in more rigorous monitoring activity, given the basic tracking and reporting requirements established by the FDA and its cost-benefit rubric; or the manufacturer might have failed to disclose relevant information to the FDA.

As part of its investigation, the FDA or advisory panel might determine when the manufacturer should have taken additional investigatory steps, and, had it done so, when and what it would have discovered, and what regulatory action the FDA would have taken in response. The finder might then be authorized to sue the manufacturer for all injuries

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<sup>119</sup> As Richard Merrill observes, “[r]ealization that a drug is more dangerous than first anticipated will not always require the FDA to reverse its original assessment of risk and benefit, even though many more persons may be imperiled by its use.” Merrill, *supra* note 8, at 16. He provides as an example the polio vaccine, arguing that “if the existing technology could not have made the product safer, public health authorities might reasonably have concluded that the benefits of general immunization against polio outweigh the unpreventable hazard of contracting the disease from the vaccine itself.” *Id.* at 15–16. In such instances, the threat of liability should not deter the manufacturer from engaging in socially beneficial activity. *See supra*, note 105.

<sup>120</sup> *See supra*, notes 53–55, and accompanying text.

attributable to any risks that should have been avoided but were not due to the manufacturer's failure, as well as for any amount the manufacturer benefited by dragging its feet.

## **Conclusion**

The regulatory alternative proposed in Part IV would have the benefit of incentivizing manufacturers to engage in optimal levels of on-going research and monitoring both before and after they have placed drugs on the market. It would do so according to a standard of negligence, but would transfer the negligence determination out of the courts into an expert agency better able to make such determinations.

Simultaneously, it would allow the FDA to determine the appropriate levels of manufacturer conduct and care. These levels would have more legitimacy than similar decisions made by juries, because they would be based on a better understanding of relevant information and a broader perspective on the relative costs and benefits of new and existing prescription drugs. They would also be more predictable, given the nature of agency decisionmaking and agency expertise, and they would therefore serve as a better predictor around which manufacturers could base their decisions to act.

This approach would avoid holding manufacturers liable for risks that they could not foresee, and should not have foreseen, at the time of FDA approval as well as throughout the market lives of their products. It would therefore avoid incentivizing firms to make their own, subjective determinations about how to value unforeseen risk.